K112192

OCT 25 2011

510(k) SUMMARY

Naturelle Daily Disposable (hilafilcon B) Cosmetically Tinted Contact Lens

1.0 Submitter Information:

Bausch & Lomb
1400 N. Goodman Street
Rochester, NY 14609
Contact: Tricia Garrett
Senior Specialist, Global Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609
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Tricia.m.garrett@bausch.com

2.0 Device Name:

Trade Name:	Bausch & Lomb Naturelle Daily Disposable (hilafilcon B) Cosmetically Tinted Contact Lens
Common Name:	soft (hydrophilic) contact lens
Device Classification:	Class II (21 CFR 886.5925 (b) (1))

3.0 Predicate Device

The predicate device is Bausch & Lomb SofLens® Daily Disposable (hilafilcon B) Visibility Tinted Contact Lens cleared in K061157 on June 22, 2006.

4.0 Device Description

The Bausch + Lomb Naturelle Cosmetically Tinted daily disposable (hilafilcon B) Contact Lens is a hemispherical flexible shell which covers the cornea and may cover a portion of the adjacent sclera. The printed ink pattern consists of a copolymer of 2-hydroxyethyl methacrylate and N-vinyl pyrrolidone, and the lens is 59% water by weight when immersed in a sterile saline solution. The lens monomer may be tinted blue with Reactive Blue Dye 246 (1,4-Bis[4-(2-methacryloxyethyl) phenylamino] anthraquinone, CFR Part 73.3106).

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5.0 Intended Use

The Bausch + Lomb Naturelle Daily Disposable (hilafilcon B) Cosmetically Tinted Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

The intended use is identical to that cleared under K061157.

6.0 Technological Characteristics (comparison to Predicate Device)

The table below shows a side-by-side comparison of the predicate device to the modified device:

Property	Bausch & Lomb SofLens® Daily Disposable (hilafilcon B) Visibility Tinted Contact Lens	Naturelle Daily Disposable (hilafilcon B) Cosmetically Tinted Contact Lens
Water Content %:	59%	Same
Refractive Index:	1.4036	
Oxygen Permeability (Dk):	22×10^{-11} [cm^3O_2(STP) x cm]/(sec x cm^2 x mmHg)@35°C (polarographic method)	
Light Transmittance:	C.I.E. Y value – approximately 95%	
Specific Gravity:	1.119	
Diameter mm:	13.5 to 15.0 mm	
Base Curve mm:	7.8 mm to 9.5 mm	
Spherical Power, Diopters:	+20.00 D to -20.00 D	
Center Thickness mm:	0.05 mm to 0.75 mm	
Print Pattern:	NA	Cosmetically Tinted Print area 8.2 to 13.0 mm

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7.0 Summary of Non-Clinical Testing

As recommended in the *FDA Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses, May 1994*, the following tests were conducted:

- Toxicology / Biocompatibility
  - ISO Ocular Irritation Study
  - ISO Systemic Toxicity
  - In-Vitro Cytotoxicity
- Chemistry / Leachables
  - Physical and Mechanical Properties
  - Leachable Monomer and Additives

The testing performed on the Bausch + Lomb Naturelle Daily Disposable (hilafilcon B) Cosmetically Tinted Contact Lens demonstrated that the device continues to function in a safe and effective manner. Performance testing included conformance to predetermined specifications, functional test results verify that the device performs as expected and is equivalent to the predicate without creating additional risk to the user.

8.0 Clinical Testing

The technological characteristics, formulation, manufacturing and sterilization processes are the same as the predicate device, therefore, no clinical studies were required to demonstrate the safety or effectiveness of the subject device.

9.0 Substantial Equivalence

The Bausch & Lomb Naturelle Daily Disposable (hilafilcon B) Cosmetically Tinted Contact Lens that is the subject of this Special 510(k) submission maintains the identical intended use, technological and functional characteristics as the predicate device. Where cosmetic differences exist between the two devices, appropriate testing has been conducted to demonstrate that the differences do not impact the safety or efficacy of the device. Bausch + Lomb Naturelle Daily Disposable (hilafilcon B) Cosmetically Tinted Contact Lens is substantially equivalent to the previously cleared Bausch & Lomb SofLens® Daily Disposable (hilafilcon B) Visibility Tinted Contact Lens cleared in K061157 on June 22, 2006.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Bausch & Lomb
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1400 North Goodman Street
Rochester, NY 14609

MAY 31 2012

Re: K112192
Trade/Device Name: Bausch & Lomb Naturelle Daily Disposable (hilafilcon B)
Cosmetically Tinted Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: MVN
Dated: September 23, 2011
Received: September 26, 2011

Dear Ms. Garrett:

This letter corrects our substantially equivalent letter of October 25, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K112192

Device Name: Bausch + Lomb Naturelle Daily Disposable (hilafilcon B) Cosmetically Tinted Contact Lens

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The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

Prescription Use ___✓____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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